MEDICSIGHT

K042674

OCT 19 2004

Appendix E

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92(c).

Submitted by:

Name:	Medicsight PLC.
Address:	46 Berkeley Square London W1J 5AT UK
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Contact:	Carol MacDonald, RA QA Director
Date of summary:	24th September 2004

Device Information:

Trade Name:	Colon CAR™ Release 1.2
Common Name:	Medical imaging software for CT scanners
Classification Name:	Computed Tomography X-Ray System, Accessory
Regulation Number:	892.1750

Predicate Device:

Medicsight Colon CAR 1.2 is substantially equivalent to the following commercially available device:

Manufacturer	Device	510(k) No.	Clearance Date
MEDICSIGHT	MedicColon 1.0	K033102	November 5th 2003

Device Description:

Colon CAR™ (Computer Assisted Reader) 1.2 is a software tool designed to assist radiologists and other clinicians in the evaluation of polyps and other lesions in the colon. The software allows the user to select regions of interest either manually or by selecting a single or double seed point, followed by semi-automatic detection of the ROI boundary. It provides 2D and 3D visualisation of polyps and measurement of polyp characteristics such as size and volume. The further feature of Colon CAR™ 1.2 as compared to the cleared device is a Polyp Enhanced Viewing Filter (PEV), the results of which are presented in a Joint Reader filter view (enhanced and non-enhanced data viewed simultaneously). The PEV filter identifies intra-colonic filling defects protruding into the colonic lumen, thereby highlighting potential polyp candidates for further interrogation by the reporting radiologist. This filter is fully adjustable and, in deciding the desired characteristics of the objects to be highlighted, the radiologist may specify the degree of object sphericity (or roundness), the height of the protruding object in relation to its base (object 'flatness') as well as select an approximate object diameter range.

Intended Use:

Colon CAR 1.2 is a PC-based, stand-alone, non-invasive, image analysis software application for the display and visualization of 2D and 3D medical image data of the colon derived from CT scans, for the purpose of assisting radiologists and other clinicians in the evaluation of polyps, cancers and other lesions. The software provides functionality for the user to extract the region of interest (ROI) either manually using a drawing tool, or "semi-automatically" through the user selecting single or double seed points followed by interactive fine-tuning the boundaries of the ROI. It also allows for the simultaneous display of supine and prone images.

Colon CAR 1.2 contains additional imaging tools which allow enhancement of specified features, and which the clinician can view simultaneously with the non-enhanced view.

Comparison to Predicate Device:

As in the predicate device, MedicColon 1.0, Colon CAR 1.2 assists users in assessing CT images for the identification and evaluation of colonic polyps.

Test data are provided to validate the performance of the system and its substantial equivalence to the predicate device. The functional features and the intended use of Colon CAR 1.2 are substantially equivalent to the predicate device. The modifications to the original device did not introduce any new potential safety risks.

Safety:

A comprehensive hazard analysis was carried out on Colon CAR 1.2, which concluded that any residual risks were as low as reasonably practicable and judged as acceptable when weighed against the intended benefits of use of the system.

Conclusion:

Colon CAR 1.2 does not raise any new potential safety risks and is equivalent in performance to the existing legally marketed device. Colon CAR 1.2 is therefore substantially equivalent with respect to safety and effectiveness to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 19 2004

Ms. Carol MacDonald
Regulatory & Quality Director
Medicsight
46 Berkeley Square
London W1J5AT
UNITED KINGDOM

Re: K042674
Trade/Device Name: Medicsight Colon CAR 1.2
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: 90 JAK
Dated: September 27, 2004
Received: September 29, 2004

Dear Ms. MacDonald:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K042674

Device Name: Medicsight Colon CAR 1.2

Indications for Use:

Colon CAR 1.2 is a PC-based, stand-alone, non-invasive, image analysis software application for the display and visualization of 2D and 3D medical image data of the colon derived from CT scans, for the purpose of assisting radiologists and other clinicians in the evaluation of polyps, cancers and other lesions. The software provides functionality for the user to extract the region of interest (ROI) either manually using a drawing tool, or "semi-automatically" through the user selecting single or double seed points followed by interactive fine-tuning the boundaries of the ROI. It also allows for the simultaneous display of supine and prone images.

Colon CAR 1.2 contains additional imaging tools which allow enhancement of specified features, and which the clinician can view simultaneously with the non-enhanced view.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K042674

Prescription Use ✓